



N2 Universal: A Case Study of an NDA

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Food and Drug Law
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N2 UNIVERSAL: A CASE STUDY OF AN NDA

The Sargenti endodontic technique has demonstrated an unequalled success rate in millions of teeth. . .1 have saved thousands of teeth at an economical cost to the patients, with predictable results and results that have not demonstrated any pulpal or other tissue necrosis from paraformaldehyde. –Dr. Emanuel Ploumis, American Endodontic Society.

Substantial scientific and clinical evidence shows that paraforinaldehyde-containing materials are cytotoxic and cause irreversible damage to living systems. –Dr. N.J. McDonald, Asst. Prof of Endodontics, University of Maryland Dental School.

It is the FDA's responsibility to determine the legality of products marketed for use in dentistry and to help make sure they are safe and effective for their intended use. –Dr. David Kessler, Commissioner of the Food and Drug Administration.¹

Food and drug law, like all areas of administrative law, is rife with tension among countervailing principles. The Food and Drug Administration is charged with protecting the health and safety of the American public. This mandate involves competing considerations. First, the FDA must ensure that drug innovation is promoted so that effective new treatments are introduced as quickly as possible and at the lowest cost possible; but, FDA must also ensure that no drugs are allowed to be marketed which may cause injury or death to a patient or which are ineffective in treating the disease for which claims are made. To allow FDA to achieve this difficult mission, Congress and the courts have given the Agency unprecedented discretion over private drug manufacturers and health care practitioners. This bureaucratic discretion is in tension with our democratic notions of due process and fairness that government should be restrained by pre-existing rules and legal principles and that each person, or drug manufacturer, should have the opportunity to participate in government actions which affect a personal, professional or financial interest.

On February 12, 1993, the Dental Products Panel of the Medical Devices Advisory Committee reported to the Commissioner of the FDA that the clinical studies and case histories submitted by N2

^t*Dental Products Panel Meeting, Volume II Dept. of Health and Human Services, Public Health Service, Food and Drug Administration, 8, 38, 40 (Feb. 12, 1993)[hereinafter *Hearing Transcrip,f'J*.*

Products Corporation in support of its NDA for N2 Universal did not meet the Agency's standards for adequate and well-controlled studies and recommended that new studies be required. This decision culminated a 10-year NDA process for the manufacturer of the drug and represented another controversial decision in a long-running and heated intra-professional battle over the use of root canal resins containing paraformaldehyde. This paper will examine the controversy over N2 Universal, focusing on the legal issues raised by its troubled passage through the FDA regulatory process, and highlighting the competing tensions of food and drug law as described above.

Endodontic Treatment: Gutta Percha vs. N2

N2 Universal is a root canal resin containing zinc-oxide, eugenol and 6.5% paraformaldehyde. It is used as a disinfectant and cement in the endodontic treatment of teeth. Endodontic treatment is performed on a tooth when it is damaged by decay or loss of circulation. The treatment is designed to prevent extraction of the tooth. It involves the removal of infected pulp from inside the tooth's canals, disinfection of the canals to kill all bacteria and to prevent future reinfection, and filling of the canal with a sealer which hardens into a cement. Endodontic treatment is performed both by specialists, endodontists, and general practitioners. The American Dental Association estimates that over 80% of endodontic services are performed by general practitioners.²

In the early 1970s, a controversy began to brew over the use of a new kind of root canal resin, now called N2 Universal or N2. Endodontists use a resin called gutta percha. It is a sealer consisting mostly of zinc-oxide and a small amount of tree sap. It is currently classified as a Class I medical device. It is not a disinfectant. Prior to filling the canal with gutta percha, endodontists disinfect the root canals with a variety of chemicals, but most commonly, sodium hypochloride (Clorox). Endodontic treatment using the gutta percha filler requires several patient visits before the tooth may be sealed, because the endodontist must disinfect the tooth several times to be sure that all bacteria have been eliminated.

The new technique, known as the Sargenti technique, was developed by a Swiss dentist, Dr. Sargenti, in the 1950s and is currently the treatment of choice in Europe and Australia. It uses the N2

² *Hearing Transcript at 54.*

root canal filler, which contains zinc-oxide, eugenol and 6.5% paraformaldehyde. The Sargenti technique does not require complete disinfection of the root canals before the tooth may be filled, since the paraformaldehyde acts as a disinfectant within the filler. Thus, the Sargenti technique may usually be completed in one visit, saving the patient time, pain and money. It is simpler than the traditional technique and has thus become the preferred technique for a great number of general practitioners in the United States.

Both techniques carry some risk of over-fill. An over-fill occurs when the dentist drills too far down the root and opens the tooth into the surrounding tissue. In a successful root canal, there is no leakage into the surrounding tissue, and the resin remains contained within the tooth. However, when an over-fill occurs, the filler leaks into the tissue, causing pain and/or tissue damage. Originally, traditional endodontists used only hand instruments to clean out the canals, minimizing the risk of over-fill but also maximizing the time and pain required to complete the root canal. Sargenti dentists use motorized devices, known as giromatics, to mechanically clean out the root canals. Thus, the root canals can be cleaned out and filled in one visit, but the risk of over-fill, particularly for a dentist with limited experience in endodontic treatment, is higher. Today, some traditional endodontists use giromatics in conjunction with gutta-percha, and some general practitioners use hand instruments in conjunction with N2. Thus, the issue, now, has become whether N2 represents a greater risk to the patient in the event of an overfill than gutta percha, although the controversy began over the inherently riskier nature of the entire Sargenti technique.

Professional Turf War: Specialists vs. Generalists

When general practitioners began using N2, the endodontists began to complain. In an article appearing in *Aw~ii~ekin* October 1975, the American Association of Endodontists (AAE) claimed that the technique was downright dangerous and stated that paraformaldehyde resembles embalming fluid [and is highly damaging to tissues. AAE asserted that the Sargenti treatment was leading to injuries to bone and oral tissues, sometimes resulting in the need for plastic surgery to undo the damage, and leading to a growing number of malpractice suits. The Sargenti users rebutted by noting that the paste contains only small amounts of potentially toxic substances [whichi

remain confined to the root canal and that the gutta-percha used by [endodontists] accounts for the postoperative pain associated with conventional treatment, while there is rarely if ever any pain experienced in the Sargenti technique.³

The *Newsweek* article was the tip of the iceberg in a battle between the specialists and general practitioners which is still raging. Since this article, others have appeared maligning the use of the Sargenti technique. In 1990, ABC's *Prime Time Live* devoted a sensationalistic segment to the Sargenti technique, charging that this stuff of nightmares only benefits the dentist, is highly toxic and that, across the country people have suffered serious and irreversible damage from Sargenti Paste. In 1991, the *Kentucky Courier-Journal* featured an article claiming that the Sargenti technique is a risky, moneymaking procedure that sacrifices safety for speed often resulting in tissue damage or long-term injury from paraformaldehyde.

In December 1975, Chairman Fountain (D-N.C.) of the House Investigating Subcommittee held a hearing on FDA's classification of N2, a new drug which presents a health hazard and should be banned.⁶ Chairman Fountain demanded that FDA regulate N2 as a drug. The American Endodontic Society (AES), an association of general practitioners who use the Sargenti technique, claim that this hearing was held at the instigation of the endodontists, who began to fear that they would lose their livelihoods if general practitioners were able to do root canals more quickly and at less cost. AES and other users of N2 believe the controversy over the Sargenti technique is an economic turf war:

We believe that this situation has evolved over the years as an economic turf war issue, where the endodontists desire to eliminate the inexpensive easily done and effective N2 endodontic technique so that more patients will be referred to their specialty. This action has been seen in a systematic combination of the non-use of N2 in many dental schools, in textbooks and in pressure exerted on journal editors not to publish N2 research that is positive; the creation of malpractice hit teams who will testify against N2 treatment in civil cases; and in direct retaliation to endodontists who favor or are

³Matt Clark, *At the Root of the Trouble*, NEWSWRN, Oct. 6, 1975, at 93.

⁴PRJMETIME LIVE, ABC News, Transcript, Feb. 8, 1990.

⁵Bob Deitel, *Dental Dilemma: Disputed Method for Root Canals Fuels Crusade*, THE COURTER-JOURNAL, March 5, 1991, at 1C.

⁶The PinkSheet, FDC REPORTS, March 8, 1993.

neutral to the use of N2. This situation is unfortunate because valuable research supporting the safety and benefits of N2 is being diminished, and the public is being discouraged from the benefits of this very effective material.⁷

The endodontists adamantly disagree with this contention, claiming that it is an issue of safety:

The judgment has been made that the risk inherent in the use of N2 or paraformaldehyde-containing paste is, in fact, unnecessary and is an unwarranted risk to patients because safe alternatives are available... Damage from paraformaldehyde is permanent when it occurs. .. It has never been a turf battle. It is purely an issue of safety. In order to protect the public the FDA must reject this application and ban the use of all paraformaldehyde-containing root canal filling materials or sealers.⁸

In the face of this professional battle, FDA was required to make an unprecedented decision—whether or not to approve the N2 root canal filler as a drug.⁹

N2 Universal's NDA: A Chronology

In 1983, N2 Products Corporation filed an NDA for N2 Universal.¹⁰ The NDA contained an

IND protocol for a clinical study, which was designed and approved by Dr. James Mann, Director of

the FDA Division of Surgical and Dental Drug Products. The protocol called for a clinical study of

100 root canals with follow-up verification of their success or failure and any adverse reactions, using a historical control.

In August 1986, Dr. Clarence Gilkes, FDA's Chief Dental Reviewing Officer of FDA notified by telephone the President of N2 Products, Dr. Alvin Artz, that all requirements of the clinical study had been fulfilled and that the clinical section of the NDA was approved. In November 1986, FDA requested additional chemistry data and stability tests for the active ingredients of N2. In August 1987, an amendment to the NDA was filed providing information on the container and closure system to be used for the finished product. In June 1990, another amendment was filed containing the chemistry and stability data requested. In March 1991, the manufacturing plant was visited for a preapproval inspection. In September 1991, Dr. Paula Botstein, Director of Division of Medical

⁷*Hearing Transcript at 58 (statement of Dr. William Fentress, American Association of Forensic Dentists).*

⁸Id. at 53-55 (statement of Dr. Joseph Maggio, Former President, American Association of Endodontists).

⁹FDA has never regulated a root canal resin or other similar dental product as a device.

¹⁰The following chronology is based upon a report written by N2 Products at-

torney, Mr. Charles Raubichek, as it appeared in the Spring 1993 Newsletter of the American Endodontic Society and is verified by testimony presented at the Dental Products Panel Hearing.

Imaging, Surgical and Dental Drug Products and Deputy Director of the Office of Drug Evaluation, requested the submission of additional case histories and further safety analysis of the clinical investigation. In April 1992, N2 Products filed an amendment to the NDA, which contained 9,514 case histories and a further safety analysis of the clinical data. In July 1992, Oscar Riggleman, FDA's chemist reviewing the NDA, indicated that the chemistry portion was approved pending inspection of the raw material manufacturers.

In December 1992, N2 Products learned from Dr. Gilkes that the NDA was being referred to the Dental Products Advisory Panel for a recommendation on approval of the clinical portion of the NDA. N2 Products was surprised by this action, since they felt that Dr. Gilkes 1986 telephone approval constituted final FDA approval of the clinical portion of the NDA. N2's attorney, Mr. Charles Raubichek, repeatedly attempted to determine the position that FDA would take at the Panel's hearing and to obtain copies of the questions which would be put to the Panel regarding the clinical study. Three days prior to the hearing, Mr. Raubichek received a list of questions challenging the propriety of the historical control in the protocol and the adequacy of the safety and effectiveness evaluations in the clinical study and case histories.

After a day-long hearing, the Dental Products Panel unanimously agreed that the clinical study submitted by N2 Products did not meet the Agency's standards for an adequate and well-controlled study. In May 1993, the FDA agreed to allow N2 Products to conduct an open field study, which will allow them to produce N2 and sell it at cost, as long as any dentist who buys it participates in the study. This is presumably an open label INID which allows general use of a drug not intended for life-threatening diseases to obtain additional information on safety and effectiveness and which are granted by FDA on an ad hoc basis.¹² N2 Products is waiting for a protocol to be approved for the open field study and for a new clinical study.

¹¹Telephone interview with Lois Artz, Board of Directors, N2 Products Corporation (Jan. 21, 1994).

¹²PEI-ER BARTON Hurr & RICHARD A. MERRILL, FOOD AND DRUG LAW, 553, 557 (2d ed. 1991) [hereinafter *Hutt casebook*].

The Dental Products Panel Decision

N2 Products and its related association, the American Endodontic Society, feel that the Panel's decision was a travesty³ and that the NDA has been handled deplorably by FDA.⁴ Many in the AES feel that FDA has been improperly influenced by the endodontists, who are better represented in the scientific and academic community than the general practitioners. They are convinced that the Panel's decision was made on political, not scientific, grounds. This raises the following questions:

Was the Panel's decision correct? illegal? unfairly biased? Did FDA handle N2's NDA improperly? FDA's Decision to Refer to the Dental Panel

Advisory committees are set up to provide FDA with information, interpretation and advice which will supplement that generated internally and to give FDA access to the highest level of scholarship in the scientific community, with state-of-the-art knowledge from individuals in research or clinical practice.⁵ They are commonly used by FDA to evaluate the adequacy of clinical studies.⁶ When Dr. Botstein began serving as Deputy Director of the Office of Drug Evaluation in 1991, she apparently became concerned about the adequacy of the clinical data in the NDA, despite the fact that it was approved by other regulators at FDA. She is neither a dentist nor an endodontist, so there is little reason to question the integrity and good-intention of this decision. In fact, her decision to refer her questions to the Panel was perfectly appropriate in this situation and preferable to denying or approving the NDA unilaterally. By referring her questions to the Panel, she ensured that all interested parties would have an opportunity for comment and that FDA would have expert advice before making a final decision on the NDA.

The Panel's Conclusion: Not an Adequate and Well-Controlled Study

³See, ~ *N2U and the FDA...A Modern Day Fairy Tale*, NEWSLETTER OF THE AMERICAN ENDODONTIC SOCIETY, Spring 1993 at 3.

~ Letter from Charles J. Raubicheck, Attorney to N2 Products, to Congressman John D. Dingell, Chauman,

Oversight and Investigations Subcommittee, Committee on Energy and Commerce, U.S. House of Representatives, March 5, 1993 (We write to make an urgent request that you investigate the FDA's truly deplorable handling of this NDA.).

¹⁵ *Use of Advisory Committees by the FDA. Statement of Commissioner Alexander Schmidt, Hearings Before a Subcommittee of the House Committee on Government Operations (1974), Huff casebook* at 1284.

¹⁶ *Huttcasebook* at 1285. See al~ 21 C.F.R. §14.160 *etseq.*

The Panel was asked to evaluate the clinical data in the NDA for N2. In the words of Dr.

Botstein:

We are asking you to evaluate the adequacy of the database that is in the NDA .. database of basically two items, a clinical study of 109 teeth in 91 patients with a historical control group taken from the literature .. .IjandIJ 9,514 case histories which were not consecutive and were apparently selected for successful Outcomes.¹⁷

This essentially amounted to a request for a determination by the Panel whether the N2 clinical study met the efficacy requirement of the Food, Drug and Cosmetic Act (FD&C Act). Section 505(d) of the FD&C Act states that the FDA shall withhold approval of a new drug unless the sponsor provides substantial evidence that the drug will have the effect it purports. Substantial evidence is defined as adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved. 18 Based upon the testimony at the hearing and the documentation in the NDA, the Panel

determined that the substantial evidence standard had not been met and, therefore, that the clinical study should not be approved.

The Panel made several conclusions:

(1) The clinical study was not adequate and well-controlled. The study protocol had not been properly documented. For example, only 8 out of 109 case forms were signed, and criteria for a determination of successful treatment were not stated. There was evidence that the cases were not completed or reported consecutively, as required by the protocol. That is, instead of each dentist reporting on the first five root canals she did upon starting the study, the dentist chose five, non-consecutive and successful root canals and reported them.¹⁹

(2) A historical control was inadequate for a study of effectiveness of root canal fillers. The Panel members felt that a simultaneous control could have been used and that the historical control used in the study had a selection bias for successful cases. 20

¹⁷ *Hearing Transcript* 117-118.

1821 U.S.C. §505(d).

¹⁹ Id. at 179.

²⁰ Id. at 181.

(3) The criteria for effectiveness were not clearly defined in either the clinical study or the his-
The patient reports in the clinical study did not have an item-by-item identification of the outcome effects to be evaluated by the monitoring dentist. 21

(4) The effectiveness endpoints were not adequately collected or analyzed. The Panel found a lack of information with regard to the endpoint, both the definition of the endpoint and the collected material, and the evidence collected was sketchy and poorly documented.²²

(5) Adverse effects had not been adequately collected, characterized or analyzed in the study or in the
Most of the historical controls have more of an anecdotal summary report of things happening than detailed information.²³

(6) The summary of the case histories did not provide controlled data on the effectiveness and safety o
Without the accompanying evidence of unsuccessful treatment, effectiveness and safety cannot be determined. 24 The Panel felt that the case histories were selected based upon success and that unsuccessful examples or adverse reactions had been purposely excluded.

In sum, the Panel concluded that:

In the absence of knowing that these are either random or consecutive cases in both the study and the historical controls so that there is not a selection bias which simply selected the successful versus the non-successful cases. .. [the Panel] has to say no.²⁵

(1) Was the Panel's Decision Correct?

Although N2 Products feels that the Panel decision was a travesty, the decision was correct. The N2 clinical study did not meet several of the FDA regulatory requirements for adequate and well-controlled studies, as set out in 21 C.F.R. § 314.26. The requirements which were not met include, but are not limited to, the following: (1) the method of assigning patients to treatment or control groups minimize bias; (2) adequate measures are taken to minimize bias on part of the observers and analysts of the data; (3) methods of assessment of subjects' response are well-defined

²¹Id at 184.

²²Id at 186.

at 192.

²⁴Id at 198.

at 200.

and reliable; and (4) the study design permits a valid comparison with a control to provide a quantitative assessment of drug effect.²⁶ Thus, the Panel had no choice but to conclude that the clinical study should not be approved.

However, even if the Panel's decision was correct according to the regulations, N2 Products and the members of the AES were understandably frustrated by the decision. In accordance with FDA procedure, the protocol followed by N2 Products in the clinical study was designed by FDA. The Panel noted that N2 Products had attempted in good faith to comply with the protocol.²⁷ Thus, the fault seems to lie with FDA for its failure to adopt an adequate protocol design. This failure was exacerbated by FDA's failure to identify the problems with the clinical study protocol much earlier in the NDA process. Since FDA has been given sole responsibility for designing INi) protocols, it has an affirmative obligation to identify problems in a protocol as they arise so that manufacturers are not misled into wasting valuable time and resources on a flawed NDA. This is particularly true where the manufacturer is small, has not had experience with the FDA's regulatory process and is, therefore, unlikely to foresee and preempt potential problems in a protocol. In this case, FDA's failures have led to ten years of lost time and money for N2 Products, and to continued uncertainty (and fear of malpractice liability) regarding the legality of the use of N2-like compounds for the general practitioners who use the Sargenti technique.

(2) Was the Panel's Decision Legal?

*Altering an Approved NDA

N2 Products claims that the FDA acted in an arbitrary and capricious manner by changing the rules in the middle of the game and reneging on an approved protocol.²⁸ The protocol established in

1983 called for one clinical study. In 1986, the FDA had seemingly approved the study, when Dr.

Gilkes of the FDA informed N2 Products that the clinical portion of the study was approved. By

1993, N2 Products had spent over ten years completing a protocol designed by FDA and complying

²⁶ 21 C.F.R. §314.26.

²⁷ *Hearmg Thanscript* at 184 (I think it is very clear that the sponsors feel they did what they were supposed to do.). *kg., Hearing Transcript* at 175 (statement of Mr. Charles Raubicheck, N2 Products attorney).

with other NDA requirements, only to be told by the Panel that the protocol was inadequate and that the study would have to be redone.

While this may be unfair to the manufacturer, it is not illegal. Section 505(e) of the FD&C Act empowers the Secretary to:

Withdraw approval of an application with respect to any drug.. . if, *[inter alia]* (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is lack of substantial evidence that the drug will have the effect it purports or is represented to have....

Although Section 505(e) is not entirely apposite, it demonstrates that the FDA has legal authority to withdraw an NDA approval, *at any time*. The decision to give FDA this authority represents a value judgment that assurance of public health and safety should take precedence over the economic costs to a manufacturer who has pursued in good faith an ultimately rejected NDA protocol. While this may make sense in terms of public protection, it may not make sense in terms of overall public health. N2 Products and the dentists using N2 claim that based on two decades of use of N2- like compounds that N2 is the quickest, least painful and cheapest way to treat root canals and that it is equally or more effective than other more traditional techniques. Even if it is not illegal for FDA to change the rules in the middle of the game, it violates fundamental principles of fairness and due process. Again, at the very least, FDA should be open about any problems it has with an NIA clinical study, immediately. By being prompt with its concerns, FDA will at least afford manufacturers the opportunity to address FDA's concerns or arrest the NDA and start over before wasting more time and money.

*1993 Standards for a 1983 Protocol

During the hearing, the Panel expressed concern about whether it was legal or fair to evaluate a study designed in 1983 by 1993 standards. One Panel member asked Dr. Botstein if they were to evaluate the study in the context of what the investigators were told initially to do versus considerations of today. 29 Dr. Botstein replied unequivocally: We have to evaluate the data before

²⁹ *Hearing Transcript at 173.*

us today. .. using the standard scientific standards of today.³⁰ While this may be legally correct, it is not necessarily correct from a policy standpoint.

FDA's drug approval process has been criticized for adding to the costs of new drugs and for leading to drug-lag, i.e., delaying the marketing of important new drugs.³¹ FDA's excessive focus on safety and effectiveness has resulted in the average NDA taking from 7 to 13 years to be approved at a cost of \$30 to \$50 million.³² Given that the NDA process now takes this long, it is bad policy for the FDA to judge clinical study protocols designed early in the process by the standards of science which exist at the end of the process. Allowing the FDA this discretion gives them carte-blanche to disapprove an NDA no matter how scrupulously the manufacturer has followed the protocol, resulting in major economic loss and delay in marketing of effective new drugs. This is particularly true for a small company like N2 Products, which could be bankrupted by such a reversal, and forced to abandon the NDA, thus depriving consumers of a potentially effective and inexpensive new drug treatment.

In addition, FDA's risk aversion exacerbates the potential ill effects of this kind of discretion. An FDA regulator will always be fearful of approving a new drug based upon old science, since if the drug then has harmful consequences, her career will be ruined.³³ Giving regulators the discretion to reject an NDA which was properly conducted under an old protocol because standards have changed is too tempting to risk-averse regulators. While the FDA does need to ensure public safety by applying the standards of state-of-the-art science, its discretion to renege on approved protocols should be restricted by Congress or agency regulations. This is particularly true for drugs which do not have life-threatening or irreversibly injurious consequences, and for small manufacturers, who may not have the resources to start an NDA over.

(3) Did FDA Handle N2's NDA Improperly?

³⁰Id. at 174.

³¹*T. Huft casebook at 580-584.*

at 514. These figures were calculated in 1980 and have increased substantially since then.

~

Huft casebook at 582.

N2 Products also claims that N2's NDA has been handled deplorably by the FDA.³⁴ Despite repeated requests, FDA refused to supply N2 Products with the Agency's questions regarding the adequacy of the clinical study until three days prior to the Panel Hearing. In addition, FDA lost all of the X-rays documenting the results of the clinical study. Although not illegal, this is clearly unprofessional and incompetent behavior, and N2 Products has a right to be incensed. The FDA should strive harder to comply with the principles of due process by informing manufacturers well in advance of Advisory Committee hearings of the issues to be discussed. There is currently no regulation requiring advanced notification of issues to be addressed at Advisory Committee hearings. Such a regulation is clearly in order. In addition, FDA should be required to make reparations for lost records and provide the manufacturer time to replicate them. If replication is not possible, FDA should be required to take into consideration its own misconduct as a mitigating factor in determining the adequacy of the records supporting a clinical study. It is unclear if the X-rays would have influenced the Panel's decision. However, since one of the Panel's primary criticisms of the study was improper documentation, the X-rays may have had some impact on the decision. It is troubling and unfair that the manufacturer was forced to pay the price of FDA's incompetence in this situation.

(4) Was the Advisory Committee Biased?

In addition to its frustration over FDA's change in position over its clinical study and its outrage at the FDA's failure to notify it of the issues to be addressed and at FDA's loss of the clinical study X-rays, N2 Products has alleged that the Panel was unfairly biased against N2.³⁵ The Federal Advisory Committee Act regulates the establishment and operations of committees advising Federal agencies.³⁶ The FDA has adopted regulations interpreting the Act which state that: An advisory committee... [shall] serve[] as a source of independent expertise and advice rather than as a representative of or advocate for any particular interest.³⁷

³⁴e **note 14, *supra*.**

³⁵See, ~L. NEWSLETTER OF THE AMERICAN ENDODONTIC SOCIETY, Spring 1993 at 2. (The decision of the Panel should be disregarded. A new, carefully selected, non-prejudiced Panel should be assembled....).

³⁶*Hutt casebook* at 1286.

~~41 Fed. Reg. 52148 (Nov. 26, 1976).

The composition of the Dental Products Panel may have violated this standard. The voting members of the Panel included: a general dentist, a professor of dental medicine, a professor of pharmacology, the Dean of the University of Washington Dental School, a professor of restorative dentistry, a professor of oral medicine, a professor of endodontics and an orthopedic surgeon. Thus, four of the eight panel members were from dental school faculties which, N2 Products and the AES claim, are controlled and dominated by the specialists, who are biased against N2. The FDA could have identified additional members of the Panel with scientific backgrounds who were not dental school faculty members to ensure an unbiased panel.

FDA should be more alert to situations where members of the health care professions feel the FDA is being unduly influenced by political considerations and should take steps to address these concerns. Failure to do so increases public concern over bureaucratic discretion and undermines public trust in FDA. As the agency with the most unfettered discretion, FDA bears a special burden to be scrupulously apolitical in making decisions such as this one. In addition, since FDA depends, in large part, upon voluntary compliance from health care practitioners with FDA regulations, it should be particularly careful to avoid actions which undermine their trust. The Agency's ability to rely on voluntary compliance will be threatened if it continues to ignore practitioners concerns about politically biased decision-making.

In defense of the FDA, however, N2 Products failed to object to the composition of the Panel before or during the hearing and has not established by concrete evidence that the dental school faculty members on the panel were, per se, biased. In addition, it would be administratively impossible for FDA to appoint a new panel each time a drug application involved intra-professional conflict. FDA did not clearly violate the letter of its regulations or the Federal Advisory Committee Act in appointing the Panel members, but it could have attempted to be more fair.

Is N2 Universal a Drug or Device?

The most perplexing issue in this case study is why N2 Universal is being regulated as a drug rather than a device. Pursuant to the Medical Device Amendments of 1976, FDA classified all medical devices at 21 C.F.R. Part 872. Under these regulations, nearly all dental products are

regulated as devices. For example, zinc oxide eugenol is Class I; gutta percha is Class I; root canal resins not containing chloroform are Class II, and those containing chloroform are Class III.³⁸ The Panel was also perplexed about why N2 was being evaluated as a drug. One panelist asked a testifying witnesses if he felt N2 was a drug or device, but was stopped by an FDA representative, who informed him that: FDA is not here to state the reasons why this product is a drug or device. A decision is made within FDA. ~ The issue arose later in the hearing when a panelist stated, I have a point of confusion. It gets back to the basic drug-device separation... I am confused about what the issues at hand are. ~ Dr. Botstein responded:

Because the paraformaldehyde is in there and because the sponsor's draft labeling talks about disinfectant, this is regarded as a drug. .. once the decision is made,

that this is a drug, ..., we do not go back and decide whether this really is a device after all, and whether it should be in the category of the other substances. We could have but we did not. The sponsor could ask us to and we would always do that again. .. We are considering the N2 Universal today as a drug because the sponsor wants to make the new drug claim that N2 disinfectsA'

Much of the problem with this NDA can be traced to the fact that no other root canal filler has ever been required to go through the drug approval process. Even dental materials containing known hazardous materials such as mercury are regulated as Class I or II medical devices.⁴² Thus, there are no standard protocols for the clinical study of dental filler drugs, and N2 Products was the unwitting victim of FDA's inexperience in this area.

Section 201(g) of the FD&C Act defines drug, *inter alia*, as (1)(C) articles (other than food) intended to affect the structure or any function of the body of man or other animals. Section 201(h) defines device, *inter alia*, as:

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component, part or accessory, which is ... (3) intended to affect the structure or function of the

³⁸ *The Grey Sheet*, FDC REPORTS, Aug. 17, 1987.

³⁹ *Hearing Transcript* at 41 (statement by Dr. Carolyn Tylanda, Executive Secretary, FDA Dental Products Panel).

⁴⁰ *Hearing Transcript* at 129-131 (statement by Ms. May Edwards, Dental Products Panel, Industry Representative).

⁴¹ *Hearing Transcript* at 132-133.

⁴² *The Gray Sheet*, FDC REPORTS, Aug. 17, 1987.

body of man or other animals and which does not achieve its primary intended purposes through chemical action within or on the body of man. .. and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

N2 is not clearly within one or the other of these definitions. FDA's position appears to be that disinfecting means it is a drug. However, disinfection contained within a root canal is not clearly a chemical action within the body, and N2 is certainly not metabolized for the achievement of its primary intended purpose. Given that other materials, such as root canal resins containing chloroforms, also disinfect and are classified as devices, it is disingenuous to claim that the disinfectant claim automatically makes it a drug. Normally, FDA classifies grey area medical products—those which are not clearly a drug or device—as devices rather than drugs.⁴³ Thus, it remains unclear why N2 is being regulated as a drug, unless it is because the manufacturer prefers drug status.

In fact, N2 Products does have something to gain by achieving new drug approval for N2. N2 Products holds a patent on N2 and thus stands to benefit financially. In addition, a major concern of the dentists using N2 is that they will face malpractice liability for using a non-FDA approved substance or that state boards of dentistry will ban the use of paraformaldehyde containing resins, based upon pressure from the specialists. However, malpractice liability could conceivably be reduced by requesting, as Dr. Botstein suggested, *supra*, that N2 be considered a device rather than a drug. This would eliminate the need to go through the extensive pre-marketing testing required for new drugs. On the other hand, switching to device status may not be as easy as Dr. Botstein implied. The FDA may not be willing to risk the public outcry if it allows N2 to be used as a device and someone is harmed, given that it has decided that there is insufficient evidence to conclude it is safe and effective as a drug. Finally, FDA approval of N2 as a drug would ensure dentists that the substance would not be banned by the states in which they practice, since a state has never banned the use of an FDA approved drug.

⁴³ *Hutt casebook* at 733.

~State boards of dentistry in California, Ohio, Florida, Missouri and Maryland have considered bans on the use of paraformaldehyde containing resins. No board has yet adopted a ban.
 \$~ *Hearing Transcript* at 55 and 111.

Practically, the current controversy and delayed NDA has had little effect on dentists who wish to use N2 Universal. In general, the FD&C Act is limited to acts which occur in inter-state commerce. Thus, FDA has allowed N2 to be used by dentists if they get it by prescription from intrastate pharmacists. While it may not be sold across state lines, it is essentially available for use by any dentist, any where. The fact that FDA allows this, however, is inconsistent and brings into question its sincerity in either (1) its belief that the product is unsafe for use or (2) its contention that the FDA's only concern is public health and safety. If FDA is convinced that the product is safe enough to allow this intra-state commerce exception, then it should either regulate N2 as a Class I or II medical device or approve the NDA. If it is not, and it truly is concerned about public health and safety, then it should not shirk its responsibilities to the public by allowing this kind of use to continue.

Conclusion

Congress and the courts have given the FDA unprecedented discretion to make decisions regarding the safety and effectiveness of new drugs. This reflects a judgment that FDA regulators should have the flexibility to make close-call decisions based upon agency expertise and to adopt creative approaches to complex situations without being second-guessed by the judiciary. This decision is not without costs. Without the oversight of judicial review, the agency is likely to skimp on the requirements of due process, and the potential for agency capture by special interests increases. The American people who come into contact with the process sense that it is undemocratic—that they have no where to go when they feel they have been unfairly treated. In the case of N2 Universal, a neutral judge would be better equipped to determine if the concern over the product's safety and effectiveness is based upon science or politics. Yet, years of judicial deference to FDA decisions have virtually eliminated this possibility, and thousands of American dentists now feel that they have been treated unfairly.

Fairness and public safety should not be at odds. FDA should strive to remember the responsibility it has to uphold standards of professionalism and due process, as well as its responsibility to protect public safety. Its failure to do so in this case has resulted in not only a loss of

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confidence in the Agency by a large group of health care practitioners but also the delay of a potentially very effective and inexpensive dental treatment.

Daubert v. Merrell Dgw Missed OPPortunity

by

Kimberly Jackson

I. Introduction

In 1923 the Court of Appeals for the District of Columbia established a standard for the admission of scientific evidence in Frye v. United States.¹

Novel scientific evidence was found to be admissible only if the underlying scientific principle or discovery is sufficiently established to have gained general acceptance in the particular field in which it belongs.² The continued validity of this test was called into question when the Federal Rules of Evidence (FRE) were passed.³ The Circuits were split over whether the Frye test had been superseded.⁴ In order to resolve the questions on the admission of scientific evidence, the Supreme Court granted certiorari to hear Daubert v. Merrell Dow Pharmaceuticals, Inc.

1 923 F. 1013 (D.C. Cir. 1923).

2 id... at 1014.

~ Public Law 93-596, 28 U.S.C. 2076. The two main rules are FRE 702 and FRE 703. FRE 702 Testimony by Experts: If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify in the form of an opinion or otherwise. FRE 703 Bases of Opinion Testimony by Experts: The facts or data in the particular case upon which an expert bases an opinion or inference may be those by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

~ Three circuits held that Frye did not survive the enactment of the FRE: 1J.ni.t~ States v. Jakobetz, 955 F.2d 786, 794-97 (2d. Cir.), ~ 955 F.2d 786 (1992); Deluca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941, 955 (3d. Cir. 1990); United States v. Baller, 519 F.2d 463, 466 (4th Cir.), Q~L..d~ni~d 423 u.s.

1019 (1975). Six Circuits found that Frye did survive including the Ninth Circuit's decision in ~iJ~r.i: Christophersen v. Allied Signal Corp.,

939 F2d. 1106, 1115-16 (5th Cir.) (per curiam) (en banc), L.d~ni~d, 112 5. Ct. 1280 (1991);.LnhLe~ States v. Two Bulls, 918 F.2d 56, 60 & n.7 (8th Cir. 1990), reh'g granted, vacated, 925 F.2d 1127 (8th Cir. 1991) (en banc); United States v. Smith, 869 F2d 348, 351 (7th Cir. 1989); United States v. Shorter, 809 F.2d 54, 59-61 (D.C. Cir.), ~LL d.enje~, 484 U.S. 817 (1987); United States v. Metzger, 778 F.2d 1195, 1203 (6th Cir. 1985), ~fL..d~ni~a, 477 U.S. 906 (1986).

~ 113 S.Ct. 2786 (1993).

Daubert v. Merrell Dow was one of many product liability cases brought against the manufacturer of Bendectin, an antinausea drug alleged to cause birth defects. The extensive litigation eventually caused the product to be pulled from the market in 1983. In order to prove causation, the cases focused on scientific evidence. Merrell Dow emphasized that more than 30 published studies involving 130,000 patients did not find any statistically significant associations between Bendectin and the sort of birth defects at

issue in Daubert v. Merrell Dow. To support their position, the plaintiffs relied on animal cells studies (*in vitro* studies), animal studies (*in vivo* studies), chemical analysis of Bendectin and other substances that are alleged to be teratogens, and reanalysis of certain published epidemiological studies.⁶ Five Circuits ruled that as a matter of law the plaintiffs' evidence was insufficient.⁷

In Daubert v. Merrell Dow, the issue was presented as whether the Frye rule of general acceptance had survived the enactment of the FRE that pertain to the admission of expert evidence. Plaintiffs' co-counsel Mary Gillick speculated that the court granted certiorari for this case rather than for the previous bendectin cases because of the explicit presentation of the continued validity of the Frye test.⁸ In their brief, the plaintiffs asked the court to decide whether, in light of the FRE, federal courts may apply the Frye rule and hold

~ Brief for the Respondent, Daubert v. Merrell Dow, 92-102).

~ Daubert v. Merrell Dow, 951 F.2d 1128 (9th Cir.); Turpin v. Merrell Dow Pharmaceuticals, Inc. 959 F.2d 1349 (6th Cir.), ~ 113 5. Ct. 84

(1992);

Brock v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307 (5th Cir. 1989);

Richardson v. Richardson-Merrell, Inc., 857 F.2d 823 (D.C. Cir. 1988),

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493 U.S. 882 (1989); Lynch v. Merrell-Nat'l Lab., 830 F.2d 1190 (1st Cir. 1987).

8 Product Liability Daily (BNA) October 20, 1992.

expert scientific testimony inadmissible if it has not attained general acceptance in the relevant scientific field. They also questioned, if the Frye test were applicable, whether it required publication in a peer-reviewed journal. They argued that Frye cannot stand as a judge-made rule of evidence independent of the FRE.

The defendant, Merrell Dow, asked the court to decide that the

FRE required expert scientific testimony to have an adequate foundation based on accepted scientific standards and processes for validating scientific claims. They argued that the plaintiffs incorrectly contended that FRE 702 only imposes two requirements for admissibility: a general determination that the expert's specialized knowledge will assist the trier of fact and a determination that the witness is a qualified expert in the field. The defendant argued that judges must determine both relevancy and adequate foundation for evidence.¹⁰

The potential importance of the *Jensen* case was recognized by the legal community as demonstrated by the filing of twenty-two amicus briefs by organizations such as the Pharmaceutical Manufacturers Association, American College of Legal Medicine, the American Medical Association, the American Tort Reform

Association, and the Carnegie Commission on Science, Technology, and Government.

Brief for Petitioner, *Jensen* (No. 92-102). 10 Brief for Respondent, *Jensen* (No. 92-102).

II. The Decision

On June 28, 1993, Justice Blackmun delivered the opinion for the Supreme Court which held for the plaintiffs by vacating the judgment of the Court of Appeals and remanding the case. The Supreme Court unanimously found that the Frye test of general

acceptance had been superseded by the FRE. The opinion stated that nothing in the text of FRE 702 which governs expert testimony establishes general acceptance as an absolute prerequisite to admissibility.¹¹

Justice Blackmun stated that the defendant did not present any clear indication that the FRE were intended to incorporate a general acceptance standard. On the contrary, the decision stated that the rigid general acceptance standard would be at odds with the liberal thrust of the FRE and its general approach of relaxing the traditional barriers to 'opinion' testimony.¹²

Six other justices joined Justice Blackmun in emphasizing that while the Frye test was superseded by the FRE, the admissibility of purportedly scientific evidence still has limits. FRE 702 provides most of the guidance for the admission of scientific evidence. It requires that the subject of an expert's testimony must be scientific ... knowledge.¹³ In the opinion, scientific was interpreted to imply a grounding in the methods and procedures of science.¹⁴ Justice Blackmun stated that the word knowledge

~' Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S.Ct. 2786, 2794 (1993).

12 *Id.* at 2794 (citing Beech Aircraft Corp. v. Rainey, 488 U.S. 153, 169 (1988)).

13 *Id.* at 2795.

¹⁴ *Id.*...

indicates more than subjective belief or unsupported speculation.’ 5 The Supreme Court acknowledged that, arguably, there are no certainties in science but that in order to qualify as ‘scientific knowledge,’ an inference or assertion must be derived by the scientific method.’⁶ The requirement that an expert’s testimony be about scientific knowledge established a standard of reliability. In a footnote, the Court explained that in a case involving scientific evidence, evidentiary reliability will be based upon scientific validity.’ 7

Justice Blackmun’s opinion stated that the relevance component of FRE 702 is found in the phrase that requires that the testimony assist the trier of fact to understand the evidence or to determine a fact in issue.’⁸ He wrote that Rule 702’s ‘helpfulness’ standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.’ ~

According to this opinion, a trial judge, pursuant to FRE 104(a).²⁰ must determine whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.²¹ The Court determined that this requires a preliminary assessment of whether

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Id... at n.9.

18 Id... at 2795.

19 id...at 2796.

20 FRE 104(a) states: Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision(b).

Relevancy conditioned on fact.] In making its determination it is not bound by the rules of evidence except those with respect to privileges.

21 113 S.Ct. at 2796.

the reasoning or methodology underlying the testimony is scientifically valid and whether that reasoning or methodology can properly be applied to the fact in issue.²²

Justice Blackmun's opinion explicitly stated that it did not presume to set out a definitive checklist for the factors that will bear on the inquiry.²³ However, he made four general observations.

The opinion explained that whether the theory or technique can be tested will ordinarily help determine scientific knowledge.²⁴ Justice Blackmun wrote that whether the theory or technique has been subjected to peer review and publication is another pertinent consideration.²⁵ He also recommended that the court consider the known or potential rate of error.²⁸ Finally, he explicitly stated that general acceptance can have a bearing on the inquiry.²⁷

Justice Blackmun's opinion did not exclusively rely on FRE 702 for the admission of scientific evidence. He also cited FRE 703 which establishes that expert opinions that are based on otherwise

inadmissible hearsay are only to be admitted if the facts or data are of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject.²⁸ In addition, the

opinion emphasized that FRE 403 permits the exclusion of otherwise relevant evidence if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or

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²⁵ Id... at 2797.

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²⁸ Id... at 2798.

misleading the jury The Supreme Court's opinion also highlighted the judge's power to determine that the evidence is insufficient and to use either the summary judgment or the directed verdict.³⁰

Chief Justice Rehnquist wrote a partial dissent even though he agreed with the majority about the status of the Frye test. He stated that the general observations are not only general but vague and abstract.³¹ Chief Justice Rehnquist cautioned that the scientific nature of the subject matter should cause the court to be careful when deciding more than necessary because our reach can so easily exceed our grasp.³² In his dissent, Chief Justice Rehnquist quoted sections of the majority opinion that attempted to define scientific knowledge and lamented that Questions arise simply from reading this part of the Court's opinion, and countless more questions will surely arise when hundreds of district judges try to apply its teaching. ..

III. Analysis

The ambiguity surrounding the definition of scientific knowledge and other related terms may partially explain why the attorneys for Merrell Dow and those for the plaintiffs are declaring victory. While it is not unusual for neither side to want to concede

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l.d.,1.

at 2799. (Rhenquist, C.J., dissenting).

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Id... at 2800.

defeat, both sides appear to have significant reasons to claim triumph.

Plaintiffs' attorney, Barry Nace, called the *P.a.l.Lb. ~i* opinion a total victory. He stated that the court said if you put together the right kind of experts, you have a fact question for the jury. He said, This Supreme Court has reaffirmed that juries can decide these issues. 34

David Shapiro, who was also an attorney for the plaintiffs, stated that the decision was a victory for the plaintiffs if only on the most simple basis – the Court of Appeals decision was vacated and the case was remanded. An affirmation would have been a

definite defeat. Mr. Shapiro added that while the decision was a victory, it was far less than they had hoped for. He explained that from their standpoint the ultimate decision would have been that FRE 702 requires only two questions to be answered affirmatively for evidence to get to a jury: first, the jury needs expert help and, second, the expert has the proper qualifications and background to be considered an expert. Mr. Shapiro stated that he believes this reading of FRE was supported by Chief Justice Rehnquist.³⁵

Merrell Dow's attorneys are also claiming victory. Charles Fried, an attorney for the defendant, disagreed with people who say that they lost because the Frye rule was not upheld. He emphasized that they did not make an effort to save the Frye rule. Mr. Fried explained that the outcome was a large, but admittedly

~, Supreme Court: 'General Acceptance' Theory of Evidence No Longer Good
Supreme Court Rules BNA Prod. Liab. Daily, June 29, 1993, at

1. ~ Interview with David Shapiro, Professor, Harvard Law School, Feb. 10, 1994.

indeterminate, role for the judge. He stated that the plaintiffs did not achieve their goal of a standard that got the evidence to the jury. The decision gives judges a role as gatekeeper and, consequently, the ability to keep the evidence from the jury. Mr. Fried said that the defense bar's dream was for a mechanical rule that would prevent the jury from hearing evidence, but that this was also not realized.³⁶

David Bernstein and Peter Huber³⁷ agree that the defendants were successful in their ultimate goal. They wrote The Bendectin Plaintiffs won a narrow technical battle in *D.ILJ.~Lt*, but they plainly lost the war. They believe that on remand, the district judge will apply the standard articulated by the Supreme Court and once again exclude the evidence. Even if the judge admits the evidence, Bernstein and Huber predict that he will use either summary judgment or directed verdict to resolve the case for the defense. They also believe that the Ninth Circuit would use the Daubert decision to overturn a district decision for the plaintiffs in this case³⁸

While both sides claim victory in Daubert, the decision may not have changed the way courts will analyze the admission of scientific evidence. When commenting upon the opinion, Richard Meserve³⁹ stated that the real test is how the lower courts apply

³⁶ Interview with Charles Fried, Professor, Harvard Law School, Feb. 10, 1994.

~ David Bernstein is an associate specializing in scientific and product liability

litigation at Crowell & Moring in Washington, D.C. Peter W. Huber is a Senior Fellow at the Manhattan Institute for Policy Research and author of Galileo's Revenge: Junk

Science in the Courtroom (Basic Books 1991)~

³⁸ David Bernstein and Peter W. Huber, Defense Perspective (1993) (on file with author).

³⁹ Richard Meserve is a partner at Covington & Burling in Washington, D.C. He was a member of the Carnegie Commission on Science, Technology and Government that filed an *amicus curiae* brief in support of neither party.

the decision. He said that he did not think that Daubert changed that

much because most courts are not applying, rigid single factor tests.⁴⁰ David Vladek⁴¹ also stated that he does not think that the case changed anything. He does not believe that ~ will restructure the way district judges assess the admission of scientific evidence because the criteria outlined by the court were not new. He gave peer review as an example of a consideration that courts were already using.⁴²

In order to determine whether D.a.i.j.k.i.r.t. has significantly changed the way judges assess the admission of scientific evidence

in food and drug product liability cases, I examined food and drug product liabilities cases that involved the admission of scientific evidence that were decided in the ten years preceding Daubert.⁴³

40 Telephone interview with Richard Meserve, partner at Covington & Burling, (July 26, 1993).

41 David Vladek is an attorney with Public Citizen. He worked with Ken Chesebro and other attorneys for the plaintiff.

42 Telephone interview with David Vladik, attorney with Public Citizen (July 19, 1993).

4~ I have purposely excluded all other Bendectin cases from my analysis. I excluded them because of the presumption that ~ub~.ri is representative of the Bendectin litigation and because it was the one that the Supreme Court decided to hear. If further analysis of the other Bendectin cases is desired, they are examined in detail in both the Petitioners and Respondents Briefs to the Supreme Court. Aside from the Bendectin cases. I have analyzed other food and drug product liability cases that focused on the admission of scientific evidence as found through Westlaw searches. The following list is of other cases that I found and why I did not include them in this discussion: Worsham v. A.H. Robins, 734 F.2d 676 (11th Cir. 1984) (questioning whether expert testimony is required to show manufacturer failed to meet the standard of care); Mazur v. Merck & Co., 742 F. Supp.. 239 (E.D. Pa. 1990) (reserving judgment on the motion to exclude plaintiff's expert testimony and partial summary judgment); Wells v. Ortho Pharmaceuticals Corporation, 788 F.2d 741 (11th Cir. 1986) (questioning whether the finding that plaintiff proved to a reasonable degree of medical certainty that manufacturer's spermicide caused birth defects was clearly erroneous); Marder v. G.D. Searle and Co., 630 F. Supp. 1087 (D.Md. 1986) (questioning whether the evidence was sufficient to establish causation. The evidence had already been admitted. The court said that it could have been denied

I looked at the cases decided prior to *Daubert* to determine whether there were any patterns in the reasoning of the courts. I discovered that the analysis of the judges could be classified into

three categories which I will call a qualified expert and helpfulness test, a balancing test with an emphasis on methodology, and a modified general acceptance test.

I examined the *Daubert* opinion to determine whether the

Supreme Court adopted any, or all, of these approaches. I found that even if the Supreme Court did not explicitly intend to incorporate these tests into the opinion, support for all three of these tests can be found.

My next step was to look at cases that rely on *Daubert* to

determine if these three approaches are still being used. I found that they are and, consequently, conclude that *Daubert* did not

significantly change the standard used by courts for the admission of scientific evidence.⁴⁴

While I focus exclusively on food and drug product liability cases that were decided before *Daubert*, my conclusions are probably applicable to other areas of novel scientific evidence that could have been decided by the Frye test. My analysis may not be relevant to cases in which the *Daubert* opinion has been extended to cover

admission but the lower court decided to let the evidence in. Therefore, the analysis is different from a strict admissibility question.) *Wheelahan v. G.D. Searle and Co.*, 814 F.2d 655, 1987 WL 267679 (4th Cir. 1990) (appealing from previously listed case); *Livshits v. Natural Y Surgical Specialties*, 1991 WL 261770 (*S.D.N.Y.* 1991) (questioning whether it was an error to allow the doctor to testify as an expert on some questions. Because the testimony was already admitted, the analysis is different.)

⁴⁴ The cases that I have examined for how *Daubert* has been interpreted are not about food and drug product liability because of the limited number of post-*Daubert* cases.

experts that did not fit within the realm of Frye's scientific evidence such as an accountant and an accidentologist.⁴⁵

A. Qualified Expert and Helpfulness Test

Under the qualified expert and helpfulness test, when a court examines the admissibility of scientific evidence, part of the analysis focuses on the qualifications of the expert to testify on a particular issue. In the second step of the analysis, the court determines whether the expert's testimony will assist the trier of fact. If an expert's proposed testimony meets both of these criteria, it has been found to be relevant. Before the *Daubert* decision, the courts relied on both case law and FRE 702 to support this approach.

1. Pre-Daubert

In *Graham v. Wyeth Laboratories*,⁴⁸ an infant plaintiff brought a personal injury suit alleging that the defendant's DTP vaccine

caused a stroke. The defendant offered the testimony of a doctor who asserted that the infant suffered the stroke before the vaccine was administered. The District Court excluded the evidence because it believed that any expert who testified about the causation had to be familiar with the working, nature, and medical literature concerning endotoxins.⁴⁷

The Court of Appeals reversed the District Court's decision to exclude this testimony. The Tenth Circuit relied on *Bridger v. Union Carbide Corp.*, 906 F.2d 1399 (10th Cir. 1990), *cert. denied*, 509 U.S. 1211 (1993), and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), *cert. denied*, 510 U.S. 1033 (1994).

Id., at 1407.

Railway Co. ~48 to find that, in order to be admitted, the offered evidence must be closely related to a particular profession, business or science and not within the common knowledge of the average layman. The witness must have

such skill, experience or knowledge in that particular field as to make it appear that his opinion would rest on substantial foundation and would tend to aid the trier of fact in his search for truth.⁴⁹

This language closely parallels that of FRE 702.

In this case, the court determined that there was no doubt that scientific evidence was needed to resolve critical issues that were beyond the knowledge of the average layman. Therefore, the issue was whether the doctor was qualified to give testimony about when the stroke occurred. In order to make this determination, the court looked at the doctor's experience as a pediatric ophthalmologist with training in neurology as it relates to the eye and the doctor's contact with the plaintiff as a treating physician.⁵⁰

The plaintiff in Amato v. Syntex Laboratories, Inc.⁵¹ brought an action alleging that her daughter's mental deficiencies were caused by defendant's defective Neo-MulI-Soy formula. Summary judgment was granted and affirmed because the courts found that plaintiff's experts were not qualified to testify on the issue of causation and, consequently, failed to establish a question of material fact.

48 355 R2d 382, 387 (6th Cir. 1966).

~ 906 F.2d at 1407.

~ No. 89-2348, 1990 WL 163941 (6th Cir. Oct. 26, 1990).

The Sixth Circuit cited FRE 702 for the proposition that the proffered witness must be qualified as an expert by knowledge, skill, experience, training or education.⁵² They cited *Manning v.*

International Mfg. Co.,⁵³ for the argument that in order to determine an expert's qualifications, the court must investigate the competence of the witness and whether the expert would aid the trier of fact.⁵⁴

The court determined that plaintiff's witnesses did not meet this standard because the experts' own testimony revealed that they were not qualified to give expert opinions about causation. Neither of the witnesses had conducted an examination of the child nor were they aware of the child's condition. This led the court to conclude that the experts could not provide competent testimony about medical causation and, therefore, would not be able to provide the fact finder with assistance on this issue.⁵⁵

In *Payton v. Abbott Labs.*,⁵⁶ the plaintiff brought a negligence action against a manufacturer of the drug diethylstilbestrol (DES) alleging that she was injured *in utero*. The defendants challenged the District Court's decision to admit the testimony of two of the plaintiff's expert witnesses on the issue of causation. The defense argued that the doctors were not qualified because they were

clinicians, not research scientists. They argued that without

52 *Id.* at *2.

53 650 F. 2d 846, 850 (6th Cir. 1981).

54 1990 WL 163941, *3 55 *Id.*

56 780 F. 2d 147 (1st Cir. 1985).

specialized knowledge of the research-type causation question at issue, neither doctor should have been allowed to testify.⁵⁷

The First Circuit agreed with the defense that FRE 702 requires an expert to possess specialized knowledge of the field in which he purports to be an expert. The court cited FRE 702 for the proposition that if scientific knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a qualified expert may testify.⁵⁸

In this case, the court emphasized that the offered doctors were qualified experts in the field of medicine and that teratology is part of the field of medicine. Therefore, the First Circuit disagreed with the defense and decided that the doctors should be allowed to testify without any more specialized knowledge. The court explained that the degree of expertise should influence the weight that the jury may place upon testimony, rather than determine the admissibility.⁵⁹

In Smith v. Ortho Pharmaceutical Corporation,⁶⁰ the plaintiffs brought a products liability action against the manufacturer of vaginal spermicide seeking recovery for a child who was born with a genetic or chromosomal abnormality. The defendant moved to preclude the testimony of plaintiffs' proposed causation experts because the type of data that they used was not reasonably relied upon by experts in determining the cause of birth defects.

⁵⁷ Id... at 155.

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⁶⁰ 770 F. Supp. 1561 (N.D. Ga. 1991).

The District Court explicitly used a two-step test based upon FRE 702 to determine the relevance of the proposed experts' testimony. They stated,

Rule 702 thus contains two prerequisites to the admissibility of expert testimony: Appropriate expertise on the part of the witness and helpfulness of the expert opinion to the trier of fact.⁶¹

In order to analyze the meaning of these requirements, the District Court looked to precedent for assistance. The court looked at other circuits because it did not find any relevant cases in its own jurisdiction. The District Court cited *Daubert v. Merrell Dow Pharmaceuticals, Inc.* for the position that the expert need only be able to aid the jury in resolving a relevant issue.⁶² The decision held that an expert must have the education and experience necessary to have knowledge of the subject matter, but that he need not have complete knowledge about the field. Therefore, the court decided that the proffered doctors qualified as experts under FRE 702 even though they were not specialists in the relevant field. The court also found that the testimony would assist the jury. Therefore, the doctor's testimony was determined to be relevant.⁶³

In Porter v. Whitehall Laboratories, Inc.,⁶⁴ plaintiff brought an action against a drug manufacturer whose ibuprofen allegedly caused renal failure. The manufacturer moved for summary judgment

⁶¹ *Id.* at 1566.

⁶² *Id.*... (citing 650 F.2d 864, 850).

⁶³ 770 F. Supp. at 1568.

⁶⁴ 791 F. Supp. 1335 (S.D. Md. 1992).

65 Id... at 1345.

66 Id... at 1343.

67 113 U.S. at 2796.

arguing that the opinions of the experts were inadmissible because they were unsupported.

In this case, the District Court did not focus extensively on the qualifications of the witnesses. Instead, the court was more concerned with the scientific basis of the opinions. The court emphasized that even though an expert is qualified, it does not mean that the opinion has sufficient scientific basis.⁶⁵ The District Court stated that FRE 702 requires the court to determine if the expert is qualified and if his testimony will assist the trier of fact. The Porter court found that this requirement mandates an examination of the foundation of the opinion.⁶⁶

2. Daubert Decision

The reasoning applied in these lower court decision closely resembles parts of the ~ decision. The qualified expert and helpfulness standard can be found in several places within the Supreme Court's opinion. The qualifications of the expert were addressed in the opinion when Justice Blackmun analyzed what constituted scientific knowledge in FRE 702. Justice Blackmun also emphasized that FRE 702 requires that the evidence or testimony must assist the trier of fact. He called this FRE 702's helpfulness standard and stated that it required a valid scientific connection to the pertinent inquiry as a precondition to admissibility.⁶⁷

Additionally, the Daubert opinion explicitly outlined a two-step admissibility test for scientific evidence when it stated,

Faced with a proffer of expert scientific testimony, then, the trial judge must determine at the outset, pursuant to Rule 104(a) whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.⁶⁸

In this passage, Justice Blackmun provided lower courts with an interpretation of 104(a) that they have used, along with the analysis of FRE 702, to employ a two-step qualification and helpfulness standard to determine relevance in their analysis of the admissibility of scientific evidence.

3. Post-Daubert

The courts in both Liu v. Yin Chine Lieu⁶⁹ and United States v. Martinez⁷⁰ relied on Justice Blackmun's interpretation of Rule 104(a) in their determination of the admissibility of expert evidence. In Liu, the court had to decide whether to allow a professional economist to testify for the plaintiff. Defendant argued that the economist's projections were speculative and not helpful to the jury. The Southern District of New York found that the two-step analysis of 'whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact' is applicable when the argument is made that the expert does not have specialized knowledge and will not help the jury even when the

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69 No. 84 Civ. 0690 (PNL), 1993 WL 478343 (S.D.N.Y., Nov. 16, 1993).

70 3 F.3d 1191 (8th Cir. 1993).

evidence is not about novel scientific theories.⁷¹ In this case the court found that some of the testimony consisted of professional, scientific or technical knowledge within the meaning of Rule 702 that would assist the jury.⁷² The witness was allowed to testify on those matters.

United States v. Martinez questioned the admissibility of DNA evidence. As part of its analysis, the court stated,

Before admitting scientific expert testimony, the court must conclude, pursuant to Federal Rules of Evidence 104(a) that the proposed testimony constitutes (a) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.⁷³

The Martinez court also focused on FRE 702's requirement that expert testimony must assist the trier of fact.⁷⁴

The determination of an expert's qualifications and helpfulness is a test that was utilized by lower courts to determine relevancy before the Supreme Court decided Daubert. The Daubert court did not explicitly state that they were adopting this standard that had been utilized by the lower courts. However, the opinion contains passages that can be read as supporting this test and the lower courts have continued to utilize the approach. All that appears to have changed about this test following Daubert is that the courts are now citing Daubert as their authority for the analysis.

~ 1993 WL 478343 at *1. (citing 113 S.Ct. at 2796).

72 1993 WL 47843 at *1

~ 3 F.3d at 1196. (citing 113 S.Ct. at 2794-2795). 74 3 F.3d at 1196.

B. Balancing Test with an Emphasis on Methodology

When a court employs a balancing test to determine reliability, it looks at a wide range of factors. The key to this test is that many different issues are examined and weighed rather than a mechanical test in which the expert testimony must meet a bright line rule.⁷⁵ Under a balancing approach, courts typically scrutinize the expert's background, the data he uses, the practice of his peers, and the publications on the topic in addition to other factors. A standard theme of this approach is an emphasis on methodology. However, rarely is methodology strictly defined. This is probably deliberate. If methodology is left ambiguous, the court can adjust its requirements on a case by case basis. For example, epidemiology may be crucial in making some causation determinations, but may not be the standard practice in other fields. Similarly, extensive data may be available for some topics, but not for others. Therefore, a reliance on methodology allows the courts to adjust their requirements. But this also means that decisions can seem to be inconsistent and unpredictable due to the malleable nature of the standard.

1. Pre-Daubert

In Smith v. Ortho Pharmaceutical Corporation,⁷⁶ the court decided that the experts' testimony was relevant under FRE 702 because the witnesses were qualified as experts and their testimony

The Frye general acceptance test is a mechanical rule. The balancing approach

for the admission of scientific evidence is usually a direct rejection of the rigidity of this rule.

⁷⁶ 770 F. Supp. 1561 (N.D. Ga. 1991).

could assist the trier of fact. However, the court found that this was not enough. The District Court held that FRE 703's requirement that the evidence be of the kind reasonably relied upon by experts in his or her field mandates that the court examine the reliability of the expert's sources.⁷⁷ The court stated.

the court has a responsibility to make an independent determination of whether the basis for an expert's opinion meets minimum standards of reliability.⁷⁸

In order to make this determination, the District Court debated whether to employ the Frye test or the balancing test utilized by some other circuits. The court decided to use a balancing test in which

the evaluation of novel scientific evidence involves a balancing of relevance, reliability and helpfulness of the evidence against the likelihood of waste of time, confusion and prejudice.⁷⁹

The District Court found that admissibility depended upon the reliability of the genetic and epidemiological data and the experts' ability to evaluate that data properly.⁸⁰ The experts' testimony was carefully analyzed in terms of methodology and what other experts in the field rely upon. The court scrutinized the studies that the proffered witnesses presented. The court found that one of the

Id... at 1569.

78

U.S... at 1571.

80 Id... at 1573.

doctor's proposed testimony reflected speculation and showed that he was not familiar with basic principles used to evaluate epidemiological studies. This led to the conclusion that the basis of his testimony was not the type that experts reasonably use to determine birth defects. His testimony was not admitted.⁸¹ The court's critique of the other doctor was not more positive. Both experts were criticized for not considering relevant epidemiologic studies and the other possible causes of disease. After a detailed examination of the methodological basis of the experts' testimony, the court explained that a consensus is not a prerequisite for admissibility, but some reliable basis for the expert's opinion is necessary.⁸²

In Payton v. Abbott Labs⁸³ the defense challenged the admissibility of the plaintiff's experts asserting that they could point to no facts or data ... of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject as required by FRE 7Q3~84 The First Circuit determined that it did not matter that neither of the proffered doctors had done systematic research in the specialized area. The court found many reasons why the doctors' basis for their opinions were sufficient including: the topic had been covered in medical school; the doctors had studied some of the articles published regarding DES and embryology; the doctors had attended lectures on the topic; they discussed the subject with researchers in the field; and they had

81 Id... at 1580.

82~

83 780 F. 2d 147 (1st Cir. 1985).

84 Id... at 156.

both treated numerous DES-exposed women and their daughters in addition to the plaintiff. The court weighed these factors and concluded that the doctors' testimony was reliable enough to allow them to testify. The court was not concerned that the defendant was able to undercut some of the foundation of the doctors' opinions. The court found that weak factual underpinnings should affect the credibility of their testimony, rather than the admissibility.⁸⁵

In Porter v. Whitehall Laboratories, Inc.,⁸⁶ the District Court interpreted FRE 703 to require that an expert may only rely on evidence on which a reasonable expert in the field would rely.⁸⁷ The court explained that in order to determine whether the particular fact or data known about the particular case is the type reasonably relied on by experts, the court must consider the methods used to arrive at the conclusions. This means that

the reasons, basis, method, or major premise of an expert's opinion must have scientific support beyond the testifying expert's own hypothesis; there must be some data or established paradigm that provides the reasonably reliable reference point for the minor premise and ultimate opinion.⁸⁸

In this case, the court found that the experts based their opinions primarily upon a temporal relationship and were not familiar with the relevant medical field. Therefore, the court balanced the extent to which the opinion might be probative versus the possible

⁸⁶ 791 F. Supp. 1335 (S.D. Ind. 1992).

⁸⁷ *Id.* at 1343. (citing United States v. Lundy, 809 F.2d 392, 395 (7th Cir. 1987)).

⁸⁸ 791 F. Supp. at 1344.

89 Id... at 1355.

90 113\$. Ct. at 2797.

prejudicial effect and decided that, because the jury might be swayed by the opinions of experts, the opinion must have some basis other than hypothesis.⁸⁹

2. Daubert Decision

When the Supreme Court held that the Frye rule had been superseded by the Federal Rules of Evidence, they chose not to replace it with another mechanical rule. Instead, they instituted a balancing test. Justice Blackmun wrote that many factors will bear on the decision whether the reasoning and methodology of an expert is acceptable and, hence, admissible. He explicitly stated that he did not want to set out a definitive checklist or test. He labeled his four criteria as general observations. The first is whether the theory or technique has been tested. The second is whether the theory or technique has been subjected to peer review and publication. Third, the courts are instructed to look at the known or potential rate of error. Finally, Justice Blackmun stated that general acceptance can still have an impact on admissibility. After stating these general guidelines, Justice Blackmun emphasized that the inquiry should be a flexible one that focuses on methodology, not conclusions.⁹⁰ The test endorsed by the Daubert opinion is a balancing one focusing on methodology rather than a mechanical rule.

3. Post-Daubert

The cases that have been decided shortly after *Daubert* indicate that the criteria outlined by Justice Blackmun can be difficult to apply. The courts have not used the factors in a uniform manner. Some have viewed them more as requirements than guidelines. Other courts have focused more on one factor to the exclusion of the others.

A few months after the *Daubert* opinion, the Seventh Circuit reviewed the District Court's decision to exclude expert testimony in *Porter*. After a review of the *Daubert* holding, the Circuit Court wrote, "The district court's approach anticipated *Daubert*'s directive."⁹¹ The Seventh Circuit emphasized that the lower court's position that an expert must be able to compare the data with a known scientific conclusion or relationship. The District Court found that if experts cannot tie their assessment of data to known scientific conclusions, based on research or studies, the testimony is not helpful to the jury.⁹² The Circuit Court also found that the District Court's analysis was consistent with the four criteria outlined by *Daubert*. The lower court did not explicitly use all four criteria because some of them were not applicable to this case. For example, the lower court noted that there was not published scientific data or evidence that linked ibuprofen to RPGN. The District Court did not directly address the general acceptance of the method used, but the experts did not identify a method by which they

⁹¹ *Porter v. Whitehall Laboratories, Inc.*, 9 F.3d 607, 614 (7th Cir. 1993). ⁹²

evaluated the data.⁹³ The Circuit Court concluded that the lower court had correctly excluded the evidence. They stated that while the District Court did not apply the exact test set forth in *Daubert*, it anticipated the Supreme Court's analysis well.⁹⁴

In *Martinez*, the Eighth Circuit focused on *Daubert*'s methodology requirements. The court quoted the passage in *Daubert* in which Blackmun wrote that the subject of the scientific testimony does not have to be known to a certainty, but it must be derived by the scientific method.⁹⁵ The Eighth Circuit then looked at the four criteria outlined by Justice Blackmun and called them the non-exclusive list of factors.⁹⁶ In this case, the court found that the Second Circuit's conclusion that the techniques of DNA profiling are reliable is still valid under the *Daubert* standard.⁹⁷ However, the Eighth Circuit stated that this was not enough to admit the evidence. The court found that *Daubert* required more than just a finding of reliability of a particular methodology. According to the Eighth Circuit, a trial judge has the duty to determine whether the specific testimony offered was derived from the application of a reliable methodology or principle in the particular case.⁹⁸

In another DNA case, the Sixth Circuit's focus was slightly different.⁹⁹ The two circuits agreed that Justice Blackmun's list of four criteria was a non-exclusive list of factors. The Sixth Circuit

⁹³ *Id.* at 615.

⁹⁴ *Id.* at 616.

⁹⁵ 3 F.3d at 1196 (citing 113 S.Ct. at 2795).

⁹⁶ 3 F.3d at 1197.

⁹⁷ *Id.*

⁹⁸ 3 F.3d at 1198.

⁹⁹ *United States v. Bonds*, 12 F.3d 540 (6th Cir. 1993).

wrote that through this list, the Daubert Court began to draw the parameters of scientific validity.¹⁰⁰ Instead of focusing on the application of a reliable methodology, the Sixth Circuit emphasized that courts are not to be concerned with the reliability of the conclusions generated by valid methods, principles and reasoning. Instead, the courts are only to determine whether the principles and methodology underlying the testimony are valid.¹⁰¹ While these two approaches may be slightly different, the outcomes will probably be the same.

The approach taken by the Fourth Circuit, however, may result in dissimilar admissibility determinations. While other courts appear to have continued the trend of *Daubert* and pre-*Daubert* cases of not explicitly defining the scientific method, the Fourth Circuit defined it as subjecting testable hypotheses to the crucible of experiment in an effort to disprove them.¹⁰² In this case about expert testimony regarding chromatographic analysis conducted on cocaine samples, the court listed the four criteria and reiterated Daubert's contention that the rule is flexible. However, the Fourth Circuit went beyond the guidelines to prescribe that An opinion that defies testing, however defensible or deeply held, is not scientific.¹⁰³ Therefore, despite the Daubert opinion listing testability as only one of four factors that are not a definitive

¹⁰⁰ *Id.* at 555.

¹⁰¹ *Id.*

¹⁰² *L&L v. Aam*, 3 F.3d 769, 773 (4th Cir. 1993).

¹⁰³

checklist,¹⁰⁴ the Fourth Circuit has made testability a requirement for the admission of scientific evidence.¹⁰⁵

Before the *Daubert* decision, several courts used a balancing approach with an emphasis on methodology to evaluate scientific evidence in food and drug product liability cases. *Daubert* solidified this approach through its strong emphasis on methodology and the four criteria that Justice Blackmun listed as guidelines. The cases after *Daubert* have continued the trend of weighing several factors when deciding whether to admit scientific evidence. While the earlier cases often used some or all of the criteria outlined in *Daubert*, the cases after the Supreme Court decision usually at least mention all four. The cases vary, however, to the degree that they emphasize one criteria over the others. Sometimes this is the right approach because it allows the court to tailor its evaluation to the individual facts. This is probably what Justice Blackmun had in mind when he called these criteria a guideline rather than a definitive checklist. In other cases, however, the court appears either to use the Supreme Court's decision as an excuse to utilize a test that it wanted to use anyway or they have simply interpreted the case differently from other jurisdictions. In any event, *Daubert* has provided a framework for the balancing approach that many

104 113 S.Ct. at 2796.

105 Another way of looking at the Fourth Circuit's opinion is not that it created an inflexible single-criterion test, but that it adopted a definitional threshold for science. Most scientists would agree that scientific principles cannot be based on nontestable hypotheses. Propositions that are not testable may or may not be true, but if they cannot be shown to be true, they cannot be relied upon to determine facts. If *Daubert* requires science, then a nontestable proposition could not be admitted into evidence as support for an asserted fact. This analysis that requires a scientific fact to be testable, detracts from Justice Blackmun's listing of testability as one of four items on a nondefinitive checklist.

courts were already applying and the decision has accentuated an emphasis on methodology.

C. Modified General Acceptance Test

The general acceptance test as outlined in *Frye* is rigid. The **1923** opinion stated,

the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.¹⁰⁶

While this appears to be a mechanical rule, before *Frye* some courts were using a more malleable general acceptance test in food and drug product liability. A general acceptance test is not flexible if the court merely focuses on whether the conclusion is generally accepted in the scientific community. There is, of course, room to adjust definitions of generally accepted and scientific community, but the standard is difficult to manipulate. However, if the courts focused not on the general acceptance of the conclusion, but purely on the general acceptance of the methodology leading up to the conclusion, this allows more room for the court to decide to admit the evidence. The flexibility of the court is also increased when general acceptance is seen as only one of many factors to be considered. The inclusion of other factors such as publication and testing works well in conjunction with the evaluation of general acceptance of the methodology.

106 293 F. 1013, 1014 (D.C. Cir. 1923).

1. Pre-Daubert

The Sixth Circuit's position on general acceptance had already changed before the *Daubert* opinion. The Sixth Circuit used to expound a test that required the proffered theory to meet a general acceptance test as exemplified in *Novak v. United States*.¹⁰⁷ This case was brought by a widow under the Federal Tort Claims Act and Swine Flu Act. The plaintiff claimed her husband's death was a result of the swine flu vaccination.

When deciding whether testimony of the expert witnesses should be allowed, the court explained that the testimony must conform to 'generally accepted explanatory theory' accepted or recognized by the relevant scientific or medical community.¹⁰⁸ The court concluded that the experts' theories were not accepted. The rejection of their articles for publication by three medical journals was cited as support for this conclusion as was the lack of other objective medical studies or reports supporting their position.¹⁰⁹ Consequently, the testimony was rejected because of the lack of support for their theory.

In *Prince v. 3M Company*,¹¹⁰ the Sixth Circuit used a less stringent requirement when the court had to determine whether to admit the evidence of an expert who wanted to testify about whether the prosthesis that had been offered into evidence was the one that had been removed from the plaintiff's leg.

107 865 F.2d 718 (6th Cir. 1989).

108 *Id.* at 722.

109 *J.* at 723.

110 No. 92-3036, 1992 WL 354034 (6th Cir. Nov. 30, 1992).

The Sixth Circuit utilized a four-part test to determine the admissibility of this evidence:

- (1) a qualified expert
- (2) testifying on a proper subject
- (3) which is in conformity to a generally accepted explanatory theory
- (4) the probative value of which outweighs its prejudicial effect.¹¹⁷

The court used this four-part test to determine that the expert did not meet the necessary criteria to be deemed a qualified expert. The evidence was also excluded because it found that the test employed by the doctor was not accepted within the scientific community.¹¹² They did not criticize his conclusion, but rather the method he used to arrive at his conclusion.

The Sixth Circuit's emphasis on the general acceptance of methodology, rather than conclusions, was found in Pharmaceutical Products, Inc.¹¹³ In this case, the plaintiff argued that the defendant's drug aggravated her myocarditis and was a substantial cause of her cardiomyopathy. The District Court denied the drug distributor's motion for judgment n.o.v. or a new trial. The distributor appealed and argued that the causation hypothesis of plaintiff's expert does not have a generally accepted scientific basis. . 114

The Sixth Circuit used the same four-part test utilized in ELio. Due to the claims made by the defendant, the court focused

111 Id... at *2 (citing Sterling v. velsicol Chem. Corp., 855 F.2d 1188, 1208 (6th Cir. 1988)).

112 1992 WL 354034 at *2.

¹¹³ 993 F.2d 528 (6th Cir. 1993).

¹¹⁴ Id., at 531.

on the third element of the test which requires conformity to a generally accepted explanatory theory. The defendant argued that the generally accepted criteria was not met because the expert did not subject his view to peer review, that he presented no epidemiological evidence, and that the treating physicians disagreed with his theory.¹¹⁶

The Sixth Circuit examined the basis of the expert's opinion including the published sources that he cited. The court concluded that the expert's testimony was sufficiently plausible to allow a jury to ground a verdict on it.¹¹⁶ The court found that the conclusion did not have to be completely accepted. An alternative view based on sound methodology that was generally accepted was sufficient to allow the evidence to go to a jury.

The Sixth Circuit was not alone in its endorsement of a general acceptance requirement for the underlying methodology. The Fifth Circuit employed a similar approach in Osburn v. Anchor Laboratories, Inc.,¹¹⁷ A suit was brought in this case against the manufacturer of veterinary chloramphenicol. The user and spouse argued that the failure to provide adequate warnings regarding the risk of fatal blood disorders from the absorption of the drug was a producing and proximate cause of the user's leukemia.

The manufacturer appealed the District Court decision on several grounds including the insufficiency of the causation evidence. The defendant argued that the ideas of the plaintiffs' expert witnesses

¹¹⁶ id...at 534.

¹¹⁷ 825 F.2d 908 (5th Cir. 1987).

were not widely accepted in the medical field and were, therefore, insufficient evidence of causation.

The Fifth Circuit explicitly stated, 'An expert's opinion need not be generally accepted in the scientific community before it can be sufficiently reliable and probative to support a jury finding.'¹⁸ However, the court argued that it was necessary for the expert to arrive at his opinion by relying upon methods that other experts in his field would reasonably rely upon in reaching their own, possibly different conclusions.'¹⁹ While the conclusions do not need to be generally accepted, the methodology must be. In this case, the court found that the expert's methodologies were those that were generally relied upon by other physicians in this area.'²⁰

2. Daubert Decision

In Daubert, the Supreme Court eliminated the rigid Frye general acceptance standard when they held that the Federal Rule of Evidence superseded the common law test. However, general acceptance was not completely eliminated from the evaluation of expert testimony because it is one of the four criteria listed by Justice Blackmun in his guidelines. U.S. v. Downing^{'21} was cited for the assertion that,

reliability assessment does not require, although it does permit, explicit identification of a relevant scientific community and an express determination of a particular degree of acceptance within that community.'²²

118 Id~ at 915.

119

120 Id...at 916.

121 753 F.2d at 1238.

122 113 S.Ct. at 2797.

This is not the only place in the opinion where an endorsement for general acceptance can be found.

Justice Blackmun's strong focus on methodology and the derivation of scientific knowledge from the scientific method¹²³ could be interpreted as mandating that the methodology must be generally accepted by the relevant scientific community. While Justice Blackmun does not require that the conclusions be deemed scientifically valid, he does mandate that reasoning or methodology underlying the testimony ... [be] scientifically valid. ...¹²⁴ Justice Blackmun also stated that the focus of the inquiry must be solely on the principles and methodology, rather than the conclusions that they generate.¹²⁵

3. Post-Daubert

In Dodd-Anderson v. Stevens,¹²⁶ the court used *flau~.ri* to determine whether the expert testimony about a dental examination was correctly decided. The court evaluated that testimony in terms of the criteria set out in Justice Blackmun's guidelines. The District Court opinion examined the testimony and the underlying support for the conclusion. The decision in the case hinged upon the court's determination that Nearly every study provided by the defendants shows that there is not a general acceptance of the connection. ...¹²⁷ Consequently, the evidence was excluded.

¹²³ *Id.*... at 2795.

¹²⁴ *Id.*... at 2796.

¹²⁵ *Id.*... at 2797.

¹²⁶ Nos. 92-1015-MLB, 92-1016-MLB, 1994 wL 26922 (D. Kan. Jan. 5, 1994).

¹²⁷ *ii* at 3.

132 113 S. Ct. at 2797.

adjust to the changes in scientific knowledge can also be rigid enough to mandate uniform application. I think that these two goals are probably, to a great extent, mutually exclusive. However, this is not to say that the Supreme Court could not have gone further towards the goal of uniform results. While some of the lower courts appear to be using all three of the tests that I have identified as being part of the Daubert standard, more consistency may have been achieved if the Supreme Court had outlined these requirements more explicitly. The general acceptance test is part of the balancing factors outlined in Justice Blackmun's general guidelines, but the interpretation of FRE 1Q4 (a) that led to the qualified expert and helpfulness standard is found in a different, and seemingly less related, part of the opinion. Justice Blackmun's guidelines could also have been more concrete. While the Court probably wanted to allow substantial flexibility, the criteria could have been outlined more strongly. The factors would have been stronger both if they were a non-exhaustive checklist of relevant factors rather than general observations and if they had been stated slightly more forcefully. For example, Justice Blackmun wrote the fact of publication (or lack thereof) in a peer-reviewed journal thus will be a relevant, though not dispositive, consideration. ... 132 The opinion could have required that, if available, peer-reviewed articles on the topic must be considered. This would mandate examination of the articles but would not be unduly prejudicial against new theories because it does not make publication a prerequisite to admission. I favor requiring certain factors to be

Id... at 2796.

considered, if they are available, without making them prerequisites so that their lack of availability does not preclude admission. The opinion does not do this because it allows the lower court judges to decide individually which factors to consider.

In Daubert, Justice Blackmun was very tentative about the Court's expertise in the area of science, and Justice Rhenquist even more so. However, the role of the judicial system is to apply laws to facts. In this case, the Supreme Court refused to come to grips with the question of what a fact is when the answer depends on science. This task was delegated to individual judges in the form of vague standards. Justice Blackmun realized that he placed significant responsibility on the lower court judges. He wrote, We are confident that federal judges possess the capacity to undertake this review.¹³³ Only time will tell if the lower court judges are able to effectively make these determinations thereby creating a workable, consistent standard or if the Supreme Court should have given them more concrete guidance.